National Cancer Institute Division of Cancer Epidemiology and Genetics Chornobyl Oversight Panel Meeting Summary and Action Items

Meeting Date:

January 8, 2001

Members Present:

Robert Hoover, Elaine Ron, Shelia Zahm (Chair)

Others Present:

Gilbert Beebe, Andre Bouville, Betsy Duane (Exec Sec), Patricia Hartge, Geoff Howe, Nick Luckyanov, Ihor Masnyk, Barbara Mulach (PMI), Sharon Miller, Jacob Robbins, Kathleen Stine,

Terry Thomas

Next Meeting:

Monday 3/5/01, 10:30am-12:30pm - EPS Conference Room 7107

Note: There will be no COP meeting in February.

Brief Summaries and Action Items:

1. Future Meetings

Dr. Zahm announced that COP meetings will be held bi-monthly. A schedule of future meetings is included at the end of these minutes.

2. Human Subjects/Ethics Training

Dr. Masnyk reported that the required training is being planned through the Columbia University contract - who will provide the instructor - and will be held in February 2001. As Dr. Wachholz needs to ensure training for the collaborators on the biorepository grant, Dr. Masnyk will contact Dr. Wachholz about piggy-backing onto the arrangements with Columbia.

3. Tri-National Meeting Summary

Dr. Thomas and Ms. Stine have pulled together summaries, action items, and recommendations from the November Tri-National Meeting. This was reviewed during the meeting; specific comments are included in the following chart of action items. The finished document should be used as widely as possible, such as part of the materials to send to the advisory groups, to Columbia, and to our Ukrainian and Belarusian collaborators; and as a list of accomplishments after this and future Tri-National Meetings to apprise Dr. Klausner annually (in lieu of quarterly reports) of the projects' progress.

Epidemiology:

• Project staff are considering a study of in utero subjects, based on a push from Ukraine to look at a cohort they have traced. However, there are questions about the potential numbers of participants that could be included (over 100,000 in Belarus), whether simple computer matching with controls is possible, whether a small sample of 1400 (in Ukraine) can yield results, and whether its inclusion in

- the original protocol warrants its completion at this time. Dr. Robbins reminded the group that this was a clinically important question, and this may be the only resource in the world.
- Exit interviews with participants (1 in 20) should be recommended, to be carried out by someone other than the initial interviewer.
- Methods paper will be the first co-authored piece from the study. Chornobyl Research Unit staff are preparing the compilation from pieces provided by appropriate authors. Group authorship is proposed, and it was suggested that a small working group be formed for each paper. These may eventually evolve into a large publications committee. The draft should be available for distribution at the end of February for consideration at the March COP meeting.

Dosimetry:

- Project staff are proposing additional research to determine accurate thyroid mass measurements. Japanese, Belarus and Ukraine measurements are not the same because different methods were used to calculate thyroid mass. To determine accurate dose, some consistency must be reached in these mass measurements.
- Joint Epidemiology/Dosimetry:
- The pretest is still too long. Dr. Bouville suggested that as all questions were important to dosimetry, perhaps they could be asked at several different times. Dr. Thomas suggested that two questionnaires could be administered to ½ of the cohort, or perhaps part of the questionnaire could be self-administered before coming to the clinic.
- Initial results from the interviews with children are available, and it appears that only those mothers of children under age 10 will need to be co-interviewed.
- Dr. Masnyk will ask Dr. Stezhko to supply dosimetry data on 1,000 subjects to compare dosimetry estimates with and without the additional data from mothers.
 Dr. Masnyk will also request each country to develop cost estimates for interviewing mothers.

Action Items	Responsible	Date Due	Due To
1. From the draft summary of the Tri-National Meeting: - Epi #1: Make recommendation clear that we are asking for a precise description of the proposed study from both countries, to include how the matching would be done and what to do next with the cohort. - Epi #2: Exit interviews need to be recommended. - Epi #4: include specifics as to how improvements occurred - Epi #5: Descriptive paper draft should be compiled of pieces provided by relevant authors. The draft should be available for distribution at the end of February for consideration at the March COP meeting.	Dr. Thomas, Ms. Stine		

- Epi #6: Add that both countries should respond to this in writing. Add to form "Who should we send results to?" - Dos #4: New proposals requiring new monies can be funded by moving \$ between REB CANS, or by sending a 1-2 page request to Dr. Fraumeni for consideration from the NCI Director's reserve.	СОР	
2. Comments on the draft document should be provided to Dr. Thomas or Ms. Stine	Dr. Beebe	
3. Draft descriptive paper should be ready by end of February to distribute to COP for March review.		

4. Thyroid Advisory Group (TAG)

- The new TAG is comprised of the Bi-National Advisory Group (BAG) plus new members. The new members are: Evelyn Bromet, Maria Demkowicz, Christina Durbak, Shirley Fry, andGenevieve Roessler. TAG members should receive a letter signed by Dr. Fraumeni thanking them for their participation in the November meetings; describing their mission; sharing with them the working protocol, the meeting summary/action items, the timeline history provided to the ACERER, and the ACERER review plus NCI's response. TAG should meet soon to review the protocol.
- The protocol changes are completed, and it was decided that two versions a readable version with changes incorporated and a strike-through version showing changes should be available. In the interest of time, a clean documents should be developed first. This should be available for distribution to the COP at the end of February for consideration at the March meeting.
- The next BAG meetings are planned for late May 2001.

Action Items	Responsible	Date Due	Due To
Draft a letter with relevant enclosures for Dr. Fraumeni's signature	Dr. Masnyk		Dr. Zahm
2. A clean, readable protocol, with changes incorporated, should be finalized by end of February, for distribution to COP for March meeting.	CRU/Ms. Duane		
Begin planning a meeting in Bethesda for protocol review			

5. Leukemia Advisory Group (LAG)

The new LAG will be advisory to the leukemia projects. The new members are: Harvey Checkoway, Bruce Chabner, Lennie Wong, and Burt Bennett. LAG members should receive a letter signed by Dr. Fraumeni thanking them for their participation in this group; describing their mission; and sharing with them the protocol. The first LAG meeting should occur this year.

Action Items	Responsible	Date Due	Due To
Draft a letter with relevant enclosures for Dr. Fraumeni's signature	Dr. Masnyk		Dr. Zahm
2. Begin planning a meeting in Bethesda for protocol review	CRU		

6. Other Items

- A list of project accomplishments, compiled from all the quarterly reports, will be generated every 6 months.
- Screening forms are now unified in both countries.
- Future Meetings: 3/5, 5/7, 9/4 (Tuesday), 10/1, 11/5